K001796

SEP - 6 2000

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Philips Medical Systems North America Company

510(k) SUMMARY

Company Name	:	Philips Medical Systems North America Company.
Address	:	710 Bridgeport Avenue Shelton, CT 06484.
Registration No.	:	1217116
Contact person	:	Peter Altman
Device (Trade) Name	:	**Gyroscan INTERA (R7.5).**
Classification Name	:	Magnetic Resonance Diagnostic Device (MRDD).
Classification	:	Class II.
Product code	:	LNH
Performance standards	:	NEMA voluntary standards, FDA MRDD guidance's, UL and IEC 601 appropriate safety standards and/or draft standards are used.
Common/Usual Name	:	**Gyroscan INTERA.**

Predicate Device(s).

The **Gyroscan INTERA (R7.5)** is the extended and enhanced version of the Gyroscan INTERA Release 7 series (FDA re. **K992533**), which is also the predicate device to which it is considered to be substantially equivalent

Intended Use.

The **Philips Gyroscan INTERA (Release 7.5)** series have the same intended use as its predicate device Gyroscan Intera (Release 7). The Gyroscan INTERA systems are indicated for use as diagnostic devices that produce transverse, sagittal, coronal and oblique cross-sectional images, spectroscopic images and/or spectra, based upon ^{1}H and ^{31}P metabolites, and that display the internal structure of the head, body or extremities. These images and/or spectra, when interpreted by a trained physician yield information that may assist in diagnosis.

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Device Description and Technological Characteristics

A. Device Description

The **Gyroscan INTERA (R7.5)** is the extended and enhanced version of the (predicate device) Gyroscan INTERA Release 7 series.

The **Gyroscan INTERA (R7.5)** is based on the same platform as its predicate device with the same technological characteristics and intended use.

The extensions and improvements deal mainly with the software.
The main differences with its predicate device are the following additions and/or enhancements of the current functionality:

- **Enhancements**:
- Reset in-plane rotation in FreeStyle Planscan. Also the geometry of a previous performed scan can be reused within the same examination session.
- B1 Uniformity correction. Correction for surface coils induced image inhomogeneity
- High-resolution multi-shot Diffusion imaging (TSE/GraSE Diffusion)
- Possibility to use synergy (phased array) coils for Diffusion imaging
- Improvement of contrast enhanced scans (3D Profile Ordering).
- **Extensions (New)**
- SyncraScan reduces scan time by measuring less phase encoding steps up to the number of synergy coil elements in combination with existing scan methods.
- Balanced FFE.
- Microscopy coils. The Microscopy coils are linear one element coils similar to the existing Cx Flexible Circular coils of which with the main differences are the diameter (47 cm and 23 cm) and their enclosure, i.e. massive (rigid) housing and not flexible

General Safety and Effectiveness.

The extensions and enhancements do not induce any other risks than already indicated for the predicate device Gyroscan INTERA Release 7 series (re.K992533).

Substantial Equivalence.

The **Gyroscan INTERA (Release 7.5)** is substantially equivalent to its predicate device Gyroscan INTERA Release 7 series (re.K992533).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2000

Peter Altman
Director of Regulatory Affairs
Philips Medical Systems
North America Company
710 Bridgeport Avenue
Shelton, CT 06484

Re: K001796
Release 7.5 Series for Philips Gyroscan MR Intera
Dated: June 12, 2000
Received: June 14, 2000
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Altman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K001796

Device Name : The **Philips Gyroscan INTERA (Release 7.5)**

Indications For Use :

The **Philips Gyroscan INTERA (Release 7.5)** series have the same intended use as its predicate device Gyroscan Intera (Release 7). The Gyroscan INTERA systems are indicated for use as diagnostic devices that produce transverse, sagittal, coronal and oblique cross-sectional images, spectroscopic images and/or spectra, based upon ^{1}H and ^{31}P metabolites, and that display the internal structure of the head, body or extremities. These images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001796